

### REMARKS

Claims 1-4, 7, 9-21, 57 and 58 are pending. In the Office Action dated November 17, 2006, the Examiner took the following action: (1) objected to the drawings; (2) rejected claim 11 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter; (3) rejected claims 1-4, 7, 9-16, 18-21, 57 and 58 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,398,956 to Coville et al. in view of U.S. Patent No. 4,695,430 to Coville et al.; and (4) rejected claim 17 under 35 U.S.C. § 103(a) as being unpatentable over the '956 patent in view of the '430 patent as applied to claims 1-4, 7, 9-16, 18-21 57 and 58, and further in view of U.S. Patent No. 5,043,590 to Strandberg, Jr. et al.

#### Objections to the Drawings

The drawings are objected to for failing to show a power module and a reservoir comprising multiple chambers. Submitted with this paper is added drawing sheet 13 illustrating these elements. The drawing is supported by the specification and claims as originally filed and therefore does not constitute new matter. The specification as filed reads as follows:

“In a preferred embodiment, a reservoir comprises two chambers separated by a barrier, such as, for example, an ion permeable membrane, salt bridge, dialysis membrane, polymer film, diffusion membrane, ionomer, e.g. Nafion from Dupont, nanoporous glass, e.g. Vycor from Corning, and/or the like. In some embodiments, one chamber contains a fluid to be contacted with the microfluidic chip. A second chamber contains a fluid in contact with an electrode and is not in fluid communication with the microfluidic chip. The barrier permits electrical communication between the two chambers, in this embodiment, and prevents fluidic communication between the chambers. In this manner, fluid entering the microfluidic chip is not altered by any effects of applying a voltage across the fluid, such as pH change.” p. 10, ln. 26 – p. 11, ln. 2.

“Further, in preferred embodiments, one or more reservoirs in the reservoir module contain an electrode for interconnection to the power module...” p. 16, lns. 3-4.

#### Rejections Under 35 U.S.C. § 112

Claim 11 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. By this amendment, claim 11 has been amended to clarify that the separation channel has low dispersion properties, overcoming the indefiniteness rejection.

### Discussion of the Disclosed Embodiment

The disclosed embodiments of the invention will now be discussed in comparison to the prior art. Of course, the discussion of the disclosed embodiments, and the discussion of the differences between the disclosed embodiments and the prior art subject matter, do not define the scope or interpretation of any of the claims. Instead, such discussed differences merely help the Examiner appreciate important claim distinctions discussed thereafter.

In some embodiments, an apparatus for separating sample and detecting target analytes includes a reservoir base to which one or more reservoirs mount. The reservoir base mounts to a microfluidic chip having a number of channels and chambers formed therein. Inlets formed in the microfluidic chip permit fluid to enter the chip from the reservoirs.

The microfluidic chip may include a separation channel having a circuitous or serpentine shape. Fluids from the reservoir move through the separation channel by means of electrosomotic flow such that components of the fluid are separated. One or more of the reservoirs may couple to a power source to facilitate electrosomotic flow. The reservoir may include two chambers with one connected to the power source and the other containing a fluid. A detector positioned within the microfluidic chip interrogates the fluid within the separation channel by, for example, exposing the fluid to light and observing any fluorescence that occurs.

### Discussion of the Cited References

The '956 patent discloses a filtration cell in which a piercing instrument (16) and a reservoir (12) mount to a support (14). The support is mounted to a base (20) having an outlet port (22) formed therein. A membrane (18) is positioned between the outlet port (22) and the support. A cross flow over the membrane is induced by creating a low pressure in the reservoir (12) such that fluid is drawn from a container (26) placed over the piercing instrument. A portion of the fluid is allowed to permeate the membrane (18) and flow out the outlet port (22).

The '956 patent does not mention a microfluidic chip or suggest how a detector could be incorporated therein. The '956 further fails to disclose any of the fluid handling structures formed in the microfluidic chip of the disclosed embodiment.

The '430 patent discloses an analytic apparatus in which fluid samples are encapsulated within cells. The cells are then processed by heating them and examining them optically. The portion of the fluid being analyzed remains at all times within the cell. The '430 patent likewise fails to disclose a microfluidic chip and the fluid handling structures formed

therein in the disclosed embodiment. The '430 patent further fails to teach a reservoir having two chambers wherein one is coupled to a power source. The '430 patent teaches that blood is tested by inserting two electrodes and measuring the conductivity of the blood. Col. 1, lns. 50-63. However, the cited passage does not mention a reservoir having two chambers nor does it mention that the reservoir is disposed in an apparatus as in the disclosed embodiment. As mentioned previously, the '430 patent teaches only the processing of fluid within discrete cells and does not disclose the fluid handling apparatus of the disclosed embodiment.

There is no teaching or suggestion to combine the '439 patent, which deals only with discrete cells, with the '956 patent, which is a simple filtration cell that provides no indication that a detector could be mounted thereto as described in the disclosed embodiment. Inasmuch as neither reference discloses a separation channel, neither reference teaches or suggests mounting a detector such that it can interrogate a separation channel. The '956 patent teaches only that fluid separated using the membrane (18) may be drained through the outlet (22). The '956 patent does not teach that detection occurs in a separation channel within the microfiltration cell. The '430 patent discloses only analyzing samples within discrete cells rather than a channel.

#### Discussion of the Claims

Turning now to the claims, differences between the cited references and the claimed invention will be pointed out.

With respect to claim 1, neither the '956 nor the '430 patents teach or suggest, whether alone or in combination, all of the limitations of claim 1, including "a reservoir module comprising: a fluid manifold base ... [and] a microfluidic chip comprising: a plurality of inlets; and a separation channel in fluid communication with at least one of said inlets; [and] a sample introduction port in fluid communication with said reservoir module and at least one of the plurality of inlets."

If the support (14) of the '956 patent is regarded as the fluid manifold base then there is no other structure corresponding to the plurality of inlets, separation channel, and sample introduction port of the microfluidic chip. The piercing instrument (16) and reservoir (12) of the '956 patent mount to the support (14) and therefore cannot be regarded as part of a microfluidic chip to which the support (14) mounts. The remaining structure of the '956 patent is simply a

membrane (18) mounted to a base (20), which do not correspond to the remaining claim elements.

With respect to claim 7, neither the '956 nor the '430 patents, whether alone or in combination, teach or suggest an apparatus as recited in the claim, including a reservoir comprising "at least two chambers, wherein one of the at least two chambers is in fluidic communication with at least one of said plurality of inlets, and the second of said at least two chambers is in electrical communication with the power module."

Claims 2-3, 9-21, 57, and 58 are dependent on allowable claim 1 and are therefore allowable.

All of the claims remaining in the application are now clearly allowable. Favorable consideration and a timely Notice of Allowance are earnestly solicited.

Respectfully submitted,

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Enclosures:

Postcard  
Check  
Fee Transmittal Sheet (+ copy)  
New Drawing Sheet (1 Sheet; Fig. 12 of 12)

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